K112975

510K(k) SUMMARY

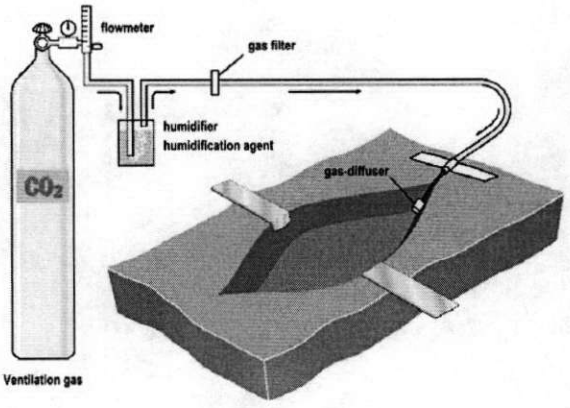
SUBMITTER:	**Cardia Innovation AB** **Lillskogsvägen 22** **S-133 34 Saltsjöbaden** **Sweden**
CONTACT PERSON:	**Dr. Jeffrey R. Shideman** **Phone : 952 835 4018**
DATE PREPARED:	**September 27th, 2011**
DEVICE NAME:	**CarbonAid® CO_2 diffuser**
CLASSIFICATION NAME:	**CarbonAid Gas diffuser**
PREDICATE DEVICE:	**Cardia Innovation AB** **CarbonAid™ gas diffuser K052125**

JUN 2 2 2012

Device Description:

The CarbonAid®CO_2 diffuser is a disposable surgical device for effective insufflation of carbon dioxide (CO_2) into an open surgical wound to create a topical atmosphere of 100% CO_2 during open heart surgery. Air will enter in the heart and great vessels during conventional open heart surgery and is difficult to evacuate with current de-airing techniques. Trapped air will be mobilized to the arterial vessels during weaning from cardiopulmonary bypass and will thus embolize to the brain and other organs. Since air dissolves poorly in blood and tissue, air bubbles will obstruct blood flow and cause tissue hypoxia and injury. CO_2 is more than 25 times more soluble than air in blood and tissue and arterial CO_2 emboli will thus be fewer, dissolve more quickly and decrease the risk of organ injury. A 100% CO_2 atmosphere can be created and maintained in an open surgical wound, since CO_2 is 50% heavier (denser) than air, provided that the CO_2 is insufflated with a low-velocity outlet device.[1-3, 5] The larger CarbonAid® CO_2 diffuser tube transports the CO_2 gas from the gas source/humidifier to the surgical wound and has the standard width / internal diameter of medical tubes for this purpose (¼ inch)

The hydrophobic gas filter (pore size ≤0.2µm) prevents cross-contamination between the gas source/humidifier* and the wound. The thinner tube contains a stainless steel wire and stabilizes the gas diffuser inside the wound. The gas diffuser is made of medical foam plastic that is connected to the thin tube via a plastic disc. The disc also provides a large bonding area for the foam plastic and encapsulates the distal end of the stainless steel wire. The gas diffuser reduces the outflow velocity of the gas thus enabling a high flow at a very low outflow velocity.



Optional external*

The elastic and hydrophobic properties of the foam plastic helps to maintain the full function of the gas diffuser and reduces the risk of foaming when the diffuser gets in contact with fluids including blood

Predicate Device:

There has been a device previously cleared by the FDA in the following 510(K) Notification indicated for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity.

Table 1.
Predicate Device

Device	510(k) Document Number	Date Cleared	Indications
Cardia Innovation AB CarbonAid™ gas diffuser	**K052125**	**2/8/2006**	intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage.

Intended Use:

Indications:

The CarbonAid® CO_2 diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage

Technological Characteristics:

Technologically, both the new device and the predicate device are the same (i.e. both are intended for the insufflation of carbon dioxide gas during open heart surgery. Any differences between the two devices do not raise new questions of safety and effectiveness

Performance Data:

Sufficient data has been gathered from testing to assess that the CarbonAid® CO_2 diffuser performs as clinically intended. Biocompatibility testing has been performed to ensure that this device, its component parts and materials are biocompatible.

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 22 2012

Cardia Innovation AB
C/O Intenational Medical Products Corporation
Jeffrey R. Shideman
7307 Glochester Drive
Edina, MN 55435

Re: K112975
CarbonAid CO_2 Diffuser
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II (two)
Product Code: HIF
Dated: May 9, 2012
Received: May 14, 2012

Dear Mr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112975

Device Name: CarbonAid®CO_2 diffuser

Indications for Use:

The CarbonAid® CO_2 diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112975